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Maik Kindermann

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### DETAILED ACTION

The amendment filed 09/08/2009 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search.

The L definition is a little garbled. Applicants inserted the word "and" before the MTX to end the list of labels, thereby to take care of point 3, but now the following "a bond..." as no role. This can be fixed by inserting before "abond" the word "or" or alternatively, "or L is".

The argument on the methotrexate issue is unpersuasive. Applicants state, "He/she would indeed look at the oxygen and nitrogen functionalities in methotrexate in order to find the best way to attach methotrexate to a linker." Applicants point to schemes 15, 16 and examples 45 and 46, all of which involve use of the primary carboxy function. However, the remarks state that this would also cover the other carboxy (the secondary COOH) as well as the nitrogen functionalities. Attachment via carbon atoms is not mentioned. How, exactly is one to know that the claims are intended to cover certain non-exemplified choices (the other COOH, and the amino), but not others?

The argument on the linkages is also unpersuasive. Applicants state, "Since the standard chemical language uses "alkyl" to indicate one free valence, "alkylene" to indicate two free valences, but has no standard expression for an alkane having three, four, ... n+1 free valences, the skilled person would conclude that "alkylene" should also be understood as a multivalent linker R4." First, this is simply not true. A trivalent carbon is called a methine, i.e. HC is methine, with three valences. Beyond that, one simply calls such things

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as they are, e.g. a trivalent alkyl radical or a tetravalent alkyl radical . See for example 4587206, where claim 3 says "R is selected from the group consisting of an alkylene group, an alkenylene group, a trivalent alkyl radical and a tetravalent alkyl radical". But even aside from that, however, applicants reasoning is a non-sequitur. One cannot infer that the L groups are not linked to each other just because chemical nomenclature lacks this or that term. One takes the terms in their normal meaning, and alkylene is divalent. The claim must be repaired.

The amendment, if entered, would have taken care of points 3-5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663.

The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Mark L. Berch/

Primary Examiner, Art Unit 1624

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